Exhibit 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 6000 Metro Drive, Suite 101 11/7/2016-11/18/2016* Baltimore, MD 21215 (410)779-5455 Fax: (410)779-5707 FEI NUMBER 1110315 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Ms. Reem Malki , Head of Global Quality Operations Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Morgantown, WV 26505-2730 Finished Drug Product Manufacturer This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above. DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: **OBSERVATION 1** Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Specifically, adequate controls have not been instituted over electronic systems in your analytical laboratories: 1. Batches are retested by analysts that may result in passing results being obtained. We observed instances of batches subject to out-of-specification (OOS), out-of-trend (OOT) and other anomalous results that were retested without any investigation. Examples include: a) Lot 3070227 of Amlodipine Besylate Tablets, 10 mg - the content uniformity testing of this batch yielded a failing result such that the USP <905> criteria was not met. Without initiating an investigation, the chemist re-injected the sample and reported the passing test result. EMPLOYEE(S) SIGNATURE DATE ISSUED Massoud Motamed, Investigato 11/18/2016 SEE REVERSE Pratik S Upadhyay, Investigated **OF THIS PAGE** Chaltu N Wakijra, Investigator Atul Agrawal, Investigator

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NAME AND TITLE OF R	NDIVIDUAL TO WHOM REPORT ISSUED			
TO: Ms. Re	em Malki , Head of Global Qual	ity Operation	ns	
FIRM NAME		STREET ADDRESS		
Mylan Pharm	aceuticals Inc.	781 Chestnu	t Ridge Rd	
CITY, STATE, ZIP CODE		TYPE ESTABLISHMENT		
Morgantown,	WV 26505-2730	Finished Dr	ug Product Manufactur	er
	This same sample set displayed "I formity.	Data Missing"	for another injection for	content uni-
b)	b) Lot 3065475 of Glyburide Tablets, 3 mg – the assay testing of this batch yielded results that failed to meet the specification of Your Director of Quality Control acknowledged the result was not within specification. Without initiating an investigation, the chemist re-injected the sample and reported the passing test result.			
с)	c) Lot 3060192 of Zonisamide Capsules, 100 mg – the assay testing of this batch yielded a failing result of Your firm's Quality Unit employees stated this result was aberrant due to a retention difference; however the failing result met your firm's specification for retention difference. Without initiating an investigation, the chemist re-injected the sample and reported the passing test result.			firm's Qual- ce; however, out initiating
d)	Lot 2006314 of Atenolol Tablets, 50 mg – the assay testing of this batch yielded an OOT result for the difference between the two assay injections, displaying a difference of Without initiating an investigation, the chemist re-injected the sample and reported the passing test result.			
e)	Lot 3070215 of Amlodipine Besyla	te Tableta 10 .	na the content uniform	ita : taatin a af
5)	this batch yielded an Subsequently, the test was repeated No investigation was cor	with passing re		
f)	Lot 3076881 of Glimepiride Tablet	ts. 1 mg – the	hlend testing of this bata	h vielded
,,	Table of Chimophide Table	o, i mg - mc		ently, the test
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TO: Ms. Re	em Malki , Head of Global Qual	ity Operation	s	
FIRM NAME	Autor	STREET ADDRESS		
Mylan Pharm	aceuticals Inc.	781 Chestnut	Ridge Rd	
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Morgantown,	WV 26505-2730	Finished Dry	NSPECTED 1g Product Manufactu	***
		Tanabaca bas	ig Froduct namitactu	.reı
	was repeated with passing results th	at did not displa	ıy.	No investiga-
	tion was conducted.			
g)	Lot 2006634 of Dextroamphetamin phetamine Sulfate & Amphetamine	e Sulfate Tablet	ts, 10 mg - the blend t	testing of this
	batch yielded	Sub	sequently, the test was	repeated with
	passing results that did not display	No	o investigation was cond	lucted.
h)	Lot 3063735 of Alfuzosin Hydroch testing for this batch displayed no with passing results. No investigation	desired peak. S	Subsequently, the test w	g – the assay as re-injected
i)	 i) Lot 3075884 of Amlodipine Besylate Tablets, 5 mg - the content uniformity testing of this batch yielded no desired peak. Subsequently, the test was re-injected with passing results. No investigation was conducted. 			
j)	j) Lot 3079153 of Amlodipine Besylate Tablets, 5 mg – the assay testing of this batch yielded no desired peak. Subsequently, the test was re-injected with passing results. No investigation was conducted.			of this batch g results. No
k)	k) Lot 2005571 of Atorvastatin Calcium Tablets, 10 mg – the dissolution testing of this batch yielded no desired peak. Subsequently, the test was rey-injected with passing re-			esting of this th passing re-
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Contract to the second	DIVIDUALTO WHOM REPORTISSUED em Malki , Head of Global Qual	ity Operation	ns	
FIRM NAME Mylan Pharma	aceuticals Inc.	781 Chestnu	t Ridge Rd	
city, state, zip code Morgantown,	COUNTRY WV 26505-2730	TYPE ESTABLISHMENT Finished Dr	INSPECTED rug Product Manufactu	rer
	sults. No investigation was conduct	ed.		
I)	 Lot 2005373 of Atorvastatin Calcium Tablets, 80 mg – the related compounds test of this batch yielded a for the initial injection (the run was not aborted). Subsequently, the test was re-injected with passing results. No investigation was conducted. 			rted). Subse-
m)	Lot 3067498 of Atenolol Tablets, 50 mg – the assay testing of this batch yielded 'for the initial injection (the sample had been injected). Subsequently, the test was re-injected with passing results. No investigation was conducted.			
n)	n) Lot 2005347 of Amlodipine and Benzapril Hydrochloride Capsules, 5 & 10 mg – the assay testing of this batch yielded for the initial injection (the run was not aborted). Subsequently, the test was re-injected with passing results. No investigation was conducted.			e run was not
Throughout the inspection, we observed additional instances of re-injecting samples due to anomalous events results with no corresponding investigation(s).				
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TO: Ms. Reem Malki , Head of Global Quality Operations			
FIRM NAME STREET ADDRESS			
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Mylan Pharmaceuticals Inc.	781 Chestnu	t Ridge Rd	
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Morgantown, WV 26505-2730	Finished Dr	ug Product Manufacturer	
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All lots specifically referenced above have been released.

2. We observed in both the Quality Control and R&D laboratories the practice of conducting injections on HPLCs and GCs prior to official analyses. Both laboratories operate under Good Manufacturing Practices, including validation studies, stability testing and finished product testing. Members of the Quality Control Unit stated that the injections conducted prior to official analyses are for the purpose of instrument setup. However, we observed many injections in both OC and R&D conducted prior to official analyses that are not identified with a name or identified in an obscure manner (e.g., "TEST," "New MP test injects LMFAO," "Medium," "Besylate ID," "lop," "0" "Single Sample," "o," "1". Based on the large number of analyses conducted, a review of all of these injections prior to official analyses was not feasible. We randomly selected and reviewed some of these injections and observed that the area values for them are similar to standards and samples run during the official analyses.

Based on samples and standards chromatograms appearing similar, there is no evidence to prove that the injections conducted prior to official analyses are not trial injections of the official samples.

3. Analysts in the Quality Control laboratory maintain the practice of altering sample sets for significant changes (e.g., sample weight, composite weight, dilution factor, etc.). Every instance of altered sample sets could not be reviewed based on the large number of instances. There is no evidence that the alterations to sample sets are reviewed to determine whether they were conducted for valid reasons and if they had/have a significant impact on the analytical results being reported. For example, we observed extensive alterations after the completion of the runs in the analysis of the following products:

a) Ketoconazole - Lots 3067506, 3062386 and 3051648; analyzed in September 2016; pa-

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Ms. Reem Malki , Head of Global Quality Operations			
FIRM NAME Mylan Pharmaceuticals Inc.	781 Chestnut Ridge Rd		
CITY, STATE, ZIP CODE COUNTRY Morgantown, WV 26505-2730	730 TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer		

rameters altered parameters include composite weight, dilution factor, number of units composited and sample weight.

- b) Valsartan HCTZ Lots 2005689; analyzed in October 2016; parameters altered include the dilution factor, sample ID, test ID, sample name, composite weight and sample weight.
- c) Felodipine Lot 3060356; analyzed in August 2016; parameters altered include the composite weight, number of units composited and sample weight.

OBSERVATION 2

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

a) The Quality Unit maintains shredding bins in the following areas: Quality Control (QC), Quality Assurance (QA), Environmental Health and Safety (EHS), Packaging and Manufacturing areas. On November 16, 2016, we found numerous documents in the shredding bins. Based on the sheer volume, each document could not be reviewed and verified during the current inspection. Examples of documents we found include:

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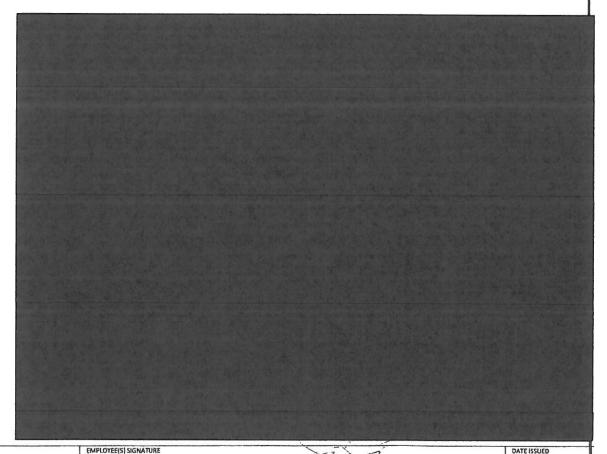
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				and the state of
OBSERVATION 3 There is a failure to the roughly review any unexplained discrepancy whether or not the batch has been				
There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.				
OOS results to	f your firm's unconfirme of and observed to be attrib glassware contammation has be is utilized to invalidate failing re	outed to "Glasswa	are Contamination." Th	is attribution of
Some Examples	s of Trending Assessments are a	is follows:		
	o dirty glassware and resolved to		2015 was opened for att nal training on glassware	cleaning.
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	Malki , Head of Global Qual	ity Operation	ns	
FIRM NAME Mylan Pharmac	euticals Inc.	781 Chestnu	t Ridge Rd	
CITY, STATE, ZIP CODE CO Morgantown, W		TYPE ESTABLISHMENT Finished Dr	ug Product Manufact	urer
OOS res ing on gl c) Trend	b) Trending Assessment opened on July 23, 2015 identifies a trend of invalidating OOS results due to an attribution to dirty glassware and recommends a laboratory-wide retraining on glassware cleaning. c) Trending Assessment opened on December 18, 2015 identifies a trend of invalidating on glassware cleaning.			
dating OOS results due to an attribution to dirty glassware and concludes that retraining on cleaning practices will occur. All trending assessments indicate that this trend had been previously identified and is an ongoing issue. In total, rending assessments identifying the attribution of OOSs to dirty glassware have been				
conducted since May of 2015.				
Coincidently, of these OOS results, at least discussed instrument malfunction and dirty glassware during analysis which led to the generation of the OOS result. It is unclear how your firm's Quality Unit invalidates OOS results when a root cause is not defined and multiple failures are implicated.				
Notably, of these OS results, at least did not report the initial failing result or mis-process the analytical data pertinent to the OOS results. Given the identification of the mis-handling of analytical data by these analysts, your Director of Analytical Investigations stated no assessment of the analyst's previous and other work had been conducted.				
(2) Your firm manufactures drug products, despite an awareness of manufacturing investigation reports and complaints related to known repeated manufacturing deficiencies. Examples of these deficiencies include:				
SEE REVERSE OF THIS PAGE	EMPLOYER(S) SIGNATURE Massoud Motamed, Investigat Pratik S Upadhyay, Investig Chaltu N Wakijra, Investigat Atul Agrawal, Investigator	ator Dan	Totaura l	DATE ISSUED 11/18/2016
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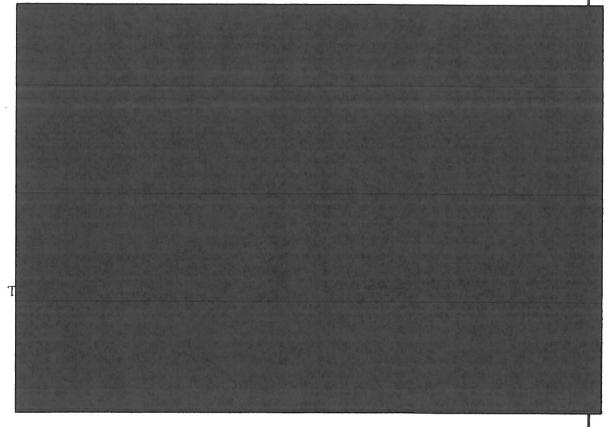
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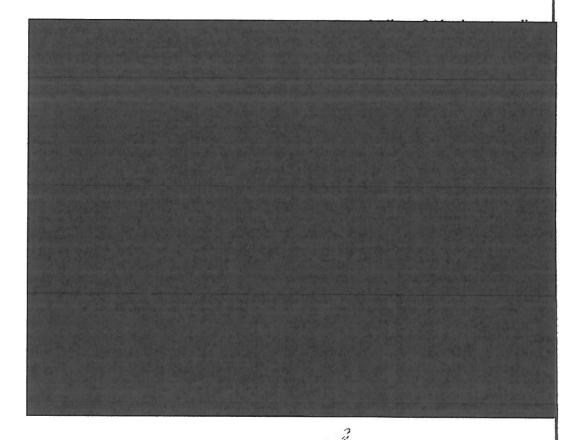
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Morgantown, WV 26505-2730	Finished Dr	rug Product Manufacturer	

OBSERVATION 4

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically,

Analysis for the following are conducted using non-validated and non-verified analytical test methods:

- a) Process Validation (PV) batches
- b) Regulatory submission batches
- c) Active Pharmaceutical Ingredients (APIs)
- d) In-process test samples
- e) Finished products

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f) Stability samples

We found instances in which your firm's R&D laboratory performed validation of test methods in time periods of several months to two years after issuance of the Certificate of Analyses (CoAs). These changes affected the parameters of the method, such that the methods may have been materially different. The following are five examples covered during the inspection:

a) Estradiol Vaginal Cream USP, 0.01% (ANDA: 208788)

Process Validation batches:

Test Name	Method	Initial Val- idation Report Dated	Current Validation Report Dated	PV/Exhibit batch test- ing Dated
	1000	10/14/15	10/20/15	
		04/02/15	09/21/15	
		03/09/15	09/23/15	
		07/24/15	10/26/15	
		05/07/15	12/15/15	

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						1110315	5			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED										
TO: Ms. Reem	Mal}	ci , Head of Global (Qualit	y Opera	ation	ıs				
FIRM NAME			T s	TREET ADDRE	22.5					
Mylan Pharmac	ceuti	cals Inc.				t Ridge	Rd			
Morgantown, V		505-2730		YPE ESTABLIS Finishe		inspected ug Prodi	ict M	anufac	turer	
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111	LC)			02/19/	113	3 04/19/16				
c) Clinda	mvcin	Palmitate Hydrochlor	ide for	Oral So	lutio	n. USP 7	/5 mg	/5ml (A	NDA - 20	3063)
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Process Validat	ion ba	tches:								
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OF THIS PAGE	Chal	tu N Wakijra, Inves	tigato		1.14	77				
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215

(410)779-5455 Fax: (410)779-5707

DATE(S) OF INSPECTION

11/7/2016-11/18/2016*

FEINUMBER 1110315

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ms. Reem Malki , Head of Global Quality Operations

FIRM NAME STREET ADDRESS

Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd

CITY, STATE, ZIP CODE, COUNTRY

TYPE ESTABLISHMENT INSPECTED

Morgantown, WV 26505-2730

Finished Drug Product Manufacturer

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	04/05/11	04/05/11	10/19/12	
	04/01/11	04/01/11	10/19/12	
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	NA	NA	10/19/12]
	04/04/11	04/05/11	10/19/12	
Iviaivem)	02/03/11	02/03/11	10/19/12	

d) <u>Dextroamphetamine Sulfate, USP API/Dextroamphetamine Sulfate Extended-Release Capsules (ANDA: 206735)</u>

Process Validation batches:

Test Name	Method	Initial Validation Report	Current Validation Report	Method Transfer (QC lab)	PV/Exhibit batch testing
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Massoud Motamed, In Pratik S Upadhyay, Chaltu N Wakijra, I Atul Agrawal, Inves	Investigator nvestigator	Thurs	oranne l	11/18/2016

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DEPARTMENT OF HEALTH AND HUMAN SERVICES						
FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax: (410)779-5707	3	DATE(S) OF INSPECTION 11/7/2016-11/18/2016*				
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Ms. Reem Malki , Head of Global Quality Operations						
Mylan Pharmaceuticals Inc.	781 Chestnut					
Morgantown, WV 26505-2730 Type ESTABLISHMENTINSPECTED Finished Drug Product Manufacturer						

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	12/17/13	12/17/13	06/02/15	
	12/18/13	12/18/13	06/02/15	
	10/30/13	10/30/13	04/23/15	
	04/06/15	04/06/15	04/22/15	
	09/11/15	09/11/15	04/23/15	
	11/25/13	11/25/13	04/23/15	
	11/25/13	11/25/13	04/23/15	

e) Memantine Hydrochloride ER Capsules, 7mg, 14mg, 21mg and 28mg (ANDA: 206032)

EMPLOYEE(S) SIGNATURE DATE ISSUED Massoud Motamed, Investigator SEE REVERSE 11/18/2016 Pratik S Upadhyay, Investigator Chaltu N Wakijra, Investigator **OF THIS PAGE** Atul Agrawal, Investigator

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INSPECTIONAL OBSERVATIONS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 11/7/2016-11/18/2016* 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax: (410)779-5707 FEI NUMBER 1110315 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Ms. Reem Malki , Head of Global Quality Operations FIRM NAME Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Morgantown, WV 26505-2730 Finished Drug Product Manufacturer

Process Validation batches:

Test Name	Method	Initial Val- idation Report	Current Validation Report	Method Transfer (QC lab)	PV/Exhibit batch testing
·		Dated	Dated	Dated	CoAs issued Dated
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		07/15/14	12/17/13	09/03/14	
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		08/20/14	12/17/13	09/23/14	
		09/18/07	12/18/13	09/18/07	
		07/03/13	10/30/13	07/15/13	
		05/31/13	04/06/15	07/15/13	
		06/11/13	09/11/15	07/15/13 پ	

SEE REVERSE OF THIS PAGE EMPLOYEE(S) SIGNATURE Massoud Motamed, Investigator Pratik S Upadhyay, Investigator Chaltu N Wakijra, Investigator

Atul Agrawal, Investigator

DATE ISSUED 11/18/2016

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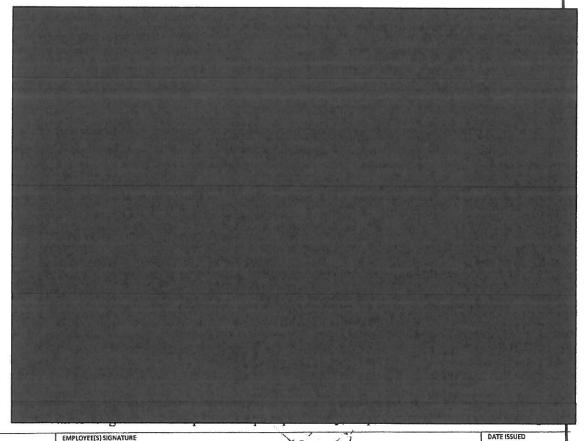
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FOOD AND DRUG ADMINISTRATION							
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Baltimore, MD							
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TO: Ms. Reem	Malki , Head of Glob	al Quali	ty	Operation	15		
FIRM NAME			STRE	ET ADDRESS			
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CITY, STATE, ZIP CODE, CO				ESTABLISHMENT			
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	1	NSPEC	TIONAL OBSERV	/ATIONS		PAGE 21 OF 23 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES						
FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax: (410)779-5707		DATE(S) OF INSPECTION 11/7/2016-11/18/2016*				
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Ms. Reem Malki , Head of Global Quality Operations						
Mylan Pharmaceuticals Inc.	781 Chestnut Ridge Rd					
CITY, STATE, ZIP CODE, COUNTRY Morgantown, WV 26505-2730	TYPEESTABLISHMENTINSPECTED Finished Drug Product Manufacturer					



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Massoud Motamed, Investigator Pratik S Upadhyay, Investigator Chaltu N Wakijra, Investigator Atul Agrawal, Investigator

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11/18/2016

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DEPARTMENT OF HEALTH AND HUMAN SERVICES						
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Ms. Reem Malki , Head of Global Quality Operations						
FIRM NAME Mylan Pharmac	euticals Inc.	781 Chestnut I	Ridge Rd			
CITY. STATE, ZIP CODE, CO Morgantown, W		TYPE ESTABLISHMENT INSP Finished Drug	ereb Product Manufacturer			
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVAT	IONS PAGE 23 OF 23 PAGES			